Caution: Federal Law (USA and Canada) restricts this device to sale by or on the order of a physician.

encore surgical

Important Information for the Operating Surgeon

Ceramic/Ceramic Total Hip System

PRODUCT DESCRIPTION AND IMPLANT MATERIALS

The Ceramic / Ceramic acetabular liners (28mm x 48/64mm and 32mm x 52/64mm diameter sizes) and femoral heads (28mm and 32mm/Neutral, +4, -4) are manufactured from aluminum oxide ceramic (alumina - ISO 6474). The metal acetabular shells used with the ceramic liner are manufactured from Ti6Al4V (ASTM F136) and are porous coated (CP titanium beads, ASTM F67) for cementless press-fit applications. The corresponding metal hip stem components used in the study are from Encore's FOUNDATION ®, Revelation® and Linear® Hip Systems that are porous-coated, semi-constrained total hip replacements intended for cementless press-fit applications.

INDICATIONS

The Ceramic/Ceramic Total Hip System is indicated for primary total hip arthroplasty in patients with the following conditions:

1) inflammatory tissue disorders; and,
2) noninflammatory degenerative joint disease including osteoarthritis, post-traumatic arthritis or secondary arthritis, and avascular necrosis.

CONTRAINDICATIONS

1) infection;
2) sepsis;
3) osteomyelitis;
4) rapid joint destruction or bone absorption apparent on roentgenogram;
5) skeletally immature patients and cases where there is a loss of abductor musculature,poor bone stock, poor skin coverage around hip joint which would make the procedure unjustifiable;
6) uncooperative patient or a patient with neurologic disorders and incapable of following instructions;
7) osteoporosis;
8) metabolic disorders which may impair bone formation;
9) osteomalacia; and
10) distant foci of infections (which may cause a hematogenous spread to the implant site);
11) obesity; and,
12) foreign body sensitivity

WARNINGS

Improper selection, placement, positioning, and fixation of the implant components may result in unusual stress conditions and a subsequent reduction in service life of the prosthetic implant. The surgeon is to be thoroughly familiar with the implant, instruments, and surgical procedure prior to performing surgery.

PRESS-FIT APPLICATIONS

Tight fixation at the time of surgery is critical to the success of the procedure. The femoral component stem must press fit into the femur, which necessitates precise operative technique and the use of specified instruments. Intraoperative fracture of the femur can occur during seating of the prosthesis. Bone stock must be adequate to support the device.

ACETABULAR FIXATION SCREWS

Caution should be exercised when using acetabular shell fixation screws to avoid the perforation of the pelvis and possible rupture of blood vessels.

MIC ACETABULAR SHELL/LINER

- Fixation screws should be fully seated to assure stable fixation of the shell, and to avoid interference with the ceramic liner which could lead to premature failure/fracture of the component.
- Prior to seating the ceramic liner into the shell component, surgical debris must be cleaned from the interior of the shell. Debris may inhibit the liner from locking into the shell component. Failure to properly seat the liner into the shell can lead to disassociation of the liner from the shell and may cause it to bind in the wrong position, chip, or be damaged.
- The ceramic liner should be placed in the shell by hand. Prior to impacting, take your finger and run along the rim to ensure the liner is even. Gently impact with the impactor provided.
- The ceramic liner should not be implanted if the liner is damaged (e.g. if the liner is dropped on the floor, or if the liner is scratched by an instrument) as this can significantly affect the structural integrity of the components.
- Replace both the ceramic liner and metal acetabular shell if the liner is chipped, cracked, or otherwise damaged during the implant procedure or postoperative timeframe. This is because the acetabular shell taper, once deformed through assembly to its mating ceramic liner, should not be reassembled to another ceramic liner.
- Do not reassemble a ceramic liner and metal acetabular shell once they have been disassembled, due to the deformation incurred by the taper locking mechanism during the initial assembly.
- Do not re-use ceramic liners. Even though the implant may appear undamaged, it may have small defects and internal stress patterns which lead to early failure/fracture of the component.

CERAMIC HEAD

- Do not use ceramic heads with components from other manufacturers because design, material, or tolerance differences may lead to premature device failure. Ceramic heads must only be used with hip stem tapers that correspond with the head tapers. Components of the system have been specifically designed to work together.
- The hip stem taper and head taper should be dry and free of all contamination to ensure proper seating and assembly. Failure to properly seat the head onto the stem can lead to disassociation of the head from the stem or may cause it to be damaged.
- The head component should be placed on the stem taper gently while keeping the head and taper in alignment, and then firmly seated by sharply hitting the head using a soft plastic hammer or impactor.
- Ceramic heads should not be implanted if the head or the cone of the stem is damaged (e.g. if the head is dropped on the floor, if the stem taper is scratched by an instrument, or if the head and stem were assembled and disassembled) as this can significantly affect the structural integrity of the component.
- Do not reassemble a ceramic head and metal stem once they have been disassembled, due to the deformation incurred by the taper locking mechanism during the initial assembly.
- If the ceramic head must be revised for any reason and the hip stem is firmly fixed, the revision should be made with a CoCr head and corresponding polyethylene liner and metal shell.
- Do not re-use ceramic heads. Even though the implant may appear undamaged, it may have small defects and internal stress patterns which lead to early failure of the device.

PRECAUTIONS

The patient must be advised of the limitation of the reconstruction and the need for protection of the implant from full weight bearing until adequate fixation and healing have occurred. Excessive activity and trauma affecting the joint replacement have been implicated with premature failure of the reconstruction by loosening, fracture and/or wear of the prosthetic implants. Loosening of the components can result in increased production of wear particles, as well as damage to the bone, making successful revision surgery more difficult. The patient should be advised to report any related pain, decrease in range of motion, swelling, fever, and unusual incidences.

The patient is to be cautioned to govern activities and protect the replaced joint from unreasonable stresses, and follow the instructions of the physician with respect to follow-up care and treatment.

The patient is to be warned of surgical risks, and made aware of possible adverse effects. The patient is to be warned that the device does not replace normal healthy bone, and that the implant can ak or become damaged as a result of strenuous activity or trauma.

ialized instruments are available and must be used to assure the accurate implantation of prosthetic components.

An implant should never be reused. While it may appear undamaged, imperfections may exist which would reduce the service life of the implant.

While rare, intraoperative fracture or breaking of instruments can occur. Instruments which have experienced extensive use or excessive force are susceptible to fracture. Instruments should be examined for wear prior to surgery.

The safety and effectiveness of the Ceramic/Ceramic Total Hip System has not been established in patients with the following conditions, or undergoing the following procedures

1) functional deformity,
2) revision procedures where other treatments or devices have failed,
3) cemented fixation; and,
4) treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement.

VERSE EFFECTS

lease refer to the Adverse Events Table, below, for the operative site adverse events reported with the use of this device system.

Table 1. Time Course Distribution of Operative Site Adverse Events for Ceramic/Ceramic Total Hip System vs. Control Ceramic/Polyethylene Hip System Out to 24 Months Post-Operatively.

Operative Site Adverse Events	Ceramic/Ceramic Original Study Population 250 cases (237 patients) enrolled						Continued Access Population 447 cases (400 patients) enrolled						Ceramic/Polyethylene Control Population 250 cases (242 patients) enrolled					
Visit	Op	6	12	24	Tot	%	Op	6	12	24	Tot	%	Op	6	12	24	Tot	%
N = cases evaluated	250	220	207	196	-	-	447	343	272	115	-	-	250	216	205	187	-	-
Revision*	0	1	0	0	1	.4%	0	1	0	1	2	.4%	0	5	0	1	6	2.4%
Fractured Liner	1	0	0	0	1	.4%	0	0	0	0	0	0%	0	0	0	0	0	0%
Clicking w/Walking	0	0	0	1	1	.4%	0	0	0	0	0	0%	0	0	0	0	0	0%
Hip Pain	2	2	1	1	6	2.4%	0	1	0	0	1	.2%	0	0	0	3	3	1.2%
Dislocation	7	0	0	0	7	2.8%	6	2	0	1	9	2%	10	0	0	0	10	4%
Fracture Femur	8	0	0	0	8	3.2%	6	0	0	0	6	1.3%	2	0	0	0	2	.8%
Trochanteric Bursitis	2	1	0	2	5	2%	0	3	1	1	5	1.1%	2	1	5	2	10	4%
Wound Infection	2	0	2	1	5	2%	1	1	0	0	2	.4%	2	0	2	0	4	1.6%
DVT	3	1	0	0	4	1.6%	1	0	0	0	1	.2%	4	0	0	0	4	1.6%
Hematoma	2	0	1	0	3	1.2%	2	0	0	0	2	.4%	1	0	0	0	1	.4%
Flexor Tendonitis	0	1	0	0	1	.4%	0	1	0	0	1	.2%	0	0	0	0	0	0%
Acetabular Cell Tumor	1	0	0	0	1	.4%	0	0	0	0	0	0%	0	0	0	0	0	0%
Heterotopic Ossification	0	1	0	0	1	.4%	0	1	1	0	2	.4%	0	3	0	0	3	1.2%
Trochanteric Wire Break	1	0	0	0	1	.4%	4	0	0	0	4	.9%	1	0	0	0	3	1.2%
Acetabular Loosening	0	0	0	0	0	0%	0	0	0	0	0	0%	1	0	0	1	2	.8%
Leg Length Inequality	0	0	0	0	0	0%	0	0	0	0	0	0%	2	0	0	0	2	.8%
Fracture Pubic Rami	0	0	0	0	0	0%	0	0	0	0	0	0%	0	0	1	0	1	.4%
Abductor Weakness	0	0	0	0	0	0%	0	0	0	0	0	0%	1	0	0	0	1	.4%
Misoriented Shell	0	0	0	0	0	0%	1	0	0	0	1	.2%	0	0	0	0	0	0%
Hip Infection	0	0	0	0	0	0%	2	0	1	0	3	.67%	0	0	0	0	0	0%
TOTAL	29	7	4	5	45		23	10	3	3	39		28	9	8	7	52	

Op = intraoperatively; 6 = 6 months; 12 =12 months; 24 = 24 months postoperative; Tot = total. Table includes **all** operative site adverse events - device related and 'unrelated'. % = total number of a particular adverse event reported divided by number of *cases enrolled*. * Revisions, included here, were not included among the operative site adverse events reported and analyzed by the sponsor. However, the adverse events that led to the revisions were reported and analyzed. The sponsor listed and analyzed revisions separately under survivorship.

General adverse effects reported for any total hip replacement surgery include:

1.) Accelerated wear of the articulating surfaces of acetabular components has been reported following total hip replacement. Such wear may be initiated by particles of cement, metal, or other debris which can cause abrasion of the articulating surfaces. Accelerated wear shortens the useful life of the prosthesis, and leads to early revision surgery to replace the worn prosthetic components.
2.) Metallosis and osteolysis may be implicated from wear debris associated with the use of orthopedic implants.
3.) Peripheral neuropathies have been reported following total joint surgery. Subclinical nerve damage occurs more frequently, possibly the result of surgical trauma.
4.) Metal sensitivity reactions in patients following joint replacement have been rarely reported. Implantation of foreign material in tissues can result in histological reactions involving macrophages and fibroblasts. The clinical significance of this effect is uncertain, as similar changes may occur as a precursor to, or during the healing process. In some cases, wear debris can initiate the process of histiocytic granuloma formation and consequent osteolysis and loosening of the implant.
5.) Dislocation and subluxation of implant components can result from improper positioning of the components. Muscle and fibrous tissue laxity can also contribute to these conditions.
6.) Implants can loosen or migrate due to trauma or loss of fixation.
7.) Infection can lead to failure of the joint replacement.
8.) While rare, fatigue fracture of the implant can occur as a result of strenuous activity, improper alignment, or duration of service.
9.) Fracture of the femur can occur while press-fitting (seating) the femoral stem component into the prepared femoral canal
10.) Allergic reactions

Intraoperative and early postoperative complications can include:

1) femoral or acetabular perforation, or fracture;
2) femoral fracture can occur while seating the device;
3) damage to blood vessels;
4) temporary or permanent nerve damage resulting in pain or numbness of the affected limb;
5) undesirable shortening or lengthening of the limb;
6) traumatic arthrosis of the knee from intraoperative positioning of the extremity;
7) cardiovascular disorders including venous thrombosis, pulmonary embolism, or myocardial infarction;
gastrointestinal complications,
genitourinary complications,
hematoma;
) delayed wound healing,
12) infection,
13) pain; and,
14) death.

Late postoperative complications can include:

1) trochanteric avulsion as a result of excess muscular weakening;
2) trochanteric non-union due to inadequate reattachment and/or early weight bearing;
3) aggravated problems of the knee or ankle of the affected limb or contralateral extremity by leg length discrepancy, too much femoral medialization, or muscle deficiency;
4) femoral fracture by trauma or excessive loading, particularly in the presence of poor bone stock;
5) periarticular calcification or ossification , with or without impediment to joint mobility;
inadequate range of motion due to improper selection or positioning of components, by femoral impingement, and periarticular calcification;
localized progressive bone resorption (osteolysis)

Study Design

The study was a prospective, multi-center, concurrently controlled clinical trial. A total of 500 cases (479 patients) were enrolled and randomized into 1 of 2 treatment groups. The investigational study group received the ceramic/ceramic hip, and the control group received a standard ceramic/polyethylene hip. Patients were followed until the last patient implanted attained their 2-year evaluation. Study patients consisted of those who had inflammatory tissue disorders (e.g. rheumatoid arthritis, lupus, etc), osteoarthritis, post-traumatic arthritis (secondary arthritis), or avascular necrosis, and less than 70 preoperative Harris Hip Score; and, were candidates for primary total hip replacement. After fulfillment of the original study enrollment, an additional 447 ceramic/ceramic devices were implanted in 400 patients under 'Continued Access'. Safety data for this group is reported in the form of adverse events in Table 1.

Clinical Patient Assessment

Each patient was evaluated at 6, 12, and 24 month post-operative time intervals. At each visit a Harris Hip Score and A/P, M/L radiographs were obtained. Radiographs were evaluated by an independent radiologist. The study endpoints consisted of a comparison of mean HHS scores, complication rates, survival rates, and radiographic failure rates (based on lucencies/migration). Success/failure of the study (i.e., of the investigational ceramic/ceramic device) was based on comparison of the results of the study endpoints for the two treatment groups. Acceptance criteria for success of the ceramic/ceramic hip system required that it would perform within 5 points or 5 percentage points of the control hip system for each of the study endpoints.

Study Population/Demographics

A total of 500 procedures were performed on 479 patients by 17 surgeons at 17 sites in the original clinical trial. A total of 250 investigational ceramic/ceramic devices were implanted into 237 patients in the original clinical trial. Over the same time period, 250 control devices were implanted in 242 patients. Forty-two patients (42) received bilateral implants, 12 received investigational devices in both hips, 9 received control devices in both hips, and 21 patients received 1 investigational and 1 control device. The primary analysis included 5 investigational patients and 8 control patients who were protocol deviations. These patients were analyzed along with the group to which they were originally randomized. The 42 bilateral patients (84 cases) were not included in the efficacy analysis for comparison of mean HHS scores. The bilateral HHS data was reported and analyzed separately, however. The bilateral patients/cases were included in the overall analysis of adverse events, device survival, and radiographic failure rates.

Table 2: Demographics

*Demographics						
Category	Female		Male		Total	
	Study	Control	Study	Control	Study	Control
Number of cases	112	133	138	117	250	250
Mean Age	55.8	61.9	54.3	59.8	55.0	60.9
Age Range	17-91	19-86	18-87	27-94	17-91	19-94
Mean Preop HHS	42.9	42.7	46.4	46.5	44.8	44.5
HHS Range	8-65	10-68	12-69	12-69	8-69	10-69
Right Hip	53	77	67	58	120	135
Left Hip	59	56	71	59	130	115

*includes bilateral cases; Study = Ceramic/Ceramic; Control = Ceramic/Polyethylene

Device Accountability

The course distribution of device accountability at each follow-up interval out to 2 years is provided in Table 3:

Table 3: Device Accountability

	Ceramic/Ceramic Study Population (n=250)			Ceramic/PE Control Population (n=250)		
	6 mo	1 yr	**>2 yrs***	6 mo	1 yr	**> 2 yrs***
Theoretical Follow-up	250	250	**250**	250	250	**250**
^Deaths	0	1	**6**	0	1	**3**
^Revisions	1	0	**1**	5	0	**6**
Expected Follow-up	249	248	**243**	245	244	**241**
Lost to Follow-Up	0	0	**14**	0	0	**26**
Actual Follow-Up %	88.3% 200/249	83.5% 207/248	**94.2% (229/243)**	87.8% 216/246	84% 205/244	**89.2% (215/241)**

Theoretical Follow-Up (TFU) = theoretical number of cases available for follow-up; Expected Follow-Up (EFU) = TFU minus deaths and revisions; Actual Follow-Up (AFU) = cases that had clinical data available at specified follow-up interval; Lost to Follow-Up (LTFU) = EFU minus AFU; AFU (%) = AFU / EFU; * includes 2 year or next available evaluation (3 or 4 year); n = number of cases; ^ cumulative from previous follow-up interval; table includes bilateral cases and protocol deviations

Safety and Effectiveness Data

Clinical testing was performed to determine if the ceramic/ceramic device was as safe and effective as the control device. Effectiveness was assessed using the Harris Hip Score. Safety was assessed according to complications, survival of the devices, and radiographic analyses. Predetermined acceptance criteria were established for each endpoint. The two treatment groups: investigational (ceramic liners) and control (polyethylene liners) were compared based on the acceptance criteria that the ceramic/ceramic hip system would perform within 5 points or 5 percentage points for each endpoint (6 percentage points for complications).

The results of the study, presented in Table 4, show that the study success criteria established to demonstrate the safety and effectiveness of the ceramic/ceramic hip system as compared to the control total hip system, were met. There were no increased risks associated with the ceramic insert. The study showed both treatment groups to be equivalent. All scores and percentages reflect the outcome at the 2-year evaluation or if a particular patient missed their 2-year evaluation, the next annual evaluation was used. There were no radiographic failures; therefore, the percentages are not indicated in the following table.

Table 4: Safety and Effectiveness Data

	Study	Control
Mean HHS Scores*	92.36	92.16
% of Patients with Related Complications	6.4%	4.8%
% of Patients with Unrelated Complications	9.2%	14.1%
Survival**	99.6%	97.2%
Radiographic Failures#	0	0

Does not include continued access data, only data from the original study population; * includes unilateral patients only (i.e. 186 study and 183 control), all other categories include bilateral patients/devices; ** lack of revision or removal; #lack of specified radiolucencies and migration

STERILIZATION

Unless opened or damaged, components are supplied sterile in triple peel pouches or double blister trays. Check all packaging for punctures or other damage. Sterilization of components is by gamma radiation to achieve a Sterility Assurance Level (SAL) of 10^{-6}. When removing the implant, appropriate aseptic procedures must be observed. The outer barrier and as appropriate, the middle barrier may be opened by non-aseptic personnel. The inner barrier must be retrieved by aseptic personnel and the implant must not come in contact with any objects that might damage the surface.

Warning: Do not autoclave any ceramic components or ceramic heads.

ım Resterilization - -FOR .ETALLIC COMPONENTS ONLY! Remove from supplied packaging and wrap in protective wrap	270° F. (132°C.) for 30 minutes Gravity Displacement Autoclave Sterility Assurance Level (SAL) of 10^{-6}

WARNING: Protect all machined tapers, coatings and polished surfaces. Standard cleaning procedures cannot be relied upon to remove contamination from plasma coating.

Key to the symbols on the labeling:

	Single use - do not reuse	STERILE R	Sterility symbol R:gamma radiation min.25 kGy
	Expiration Date	non-sterile	Non-sterile symbol :nonsterile
LOT	Lot number	Qty.	Quantity of items in package
			See "Instructions for Use"

For further information regarding the use of the ENCORE® Ceramic / Ceramic Acetabular components, contact your ENCORE® representative or distributor.
ENCORE MEDICAL, L.P., 9800 Metric Blvd., Austin, TX 78758 USA (Made in the USA)
FOUNDATION®, LINEAR®, KEYSTONE®, are registered trademarks of Encore Medical Corporation, Austin, TX 78758 USA or its affiliates.

0400-0082